IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of	Group Art Unit: 1772
Yasushi Kinoshita et al.	Examiner: Michael C. Miggins
Application No.: 10/632,952	Confirmation No.: 4467
Filed: August 4, 2003	
For: BALLOON CATHETER	

REQUEST FOR RECONSIDERATION

Okay to enter mcm 12/5/05

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the Official Action dated September 23, 2005, favorable reconsideration of this application is respectfully requested for at least the following reasons.

The top of page two of the Official Action indicates that copies of the two international application publications cited in the Information Disclosure Statement filed on August 4, 2003 were not submitted with the Information Disclosure Statement. However, as explained in the previously submitted response, copies of the two international application publications can be found in the Patent Office's electronic database for this application. The undersigned telephoned Examiner Miggins on November 8, 2005 to discuss this matter. The undersigned explained that included amongst the electronic documents for this application in the Patent Office's PAIR system are the two international application publications submitted with the August 4, 2003 Information Disclosure Statement. Examiner Miggins kindly checked the Examiner's version of the Patent Office's electronic database once again and indicated that the two international application publications are now

present. Examiner Miggins thus asked the undersigned to submit a copy of the previously submitted Information Disclosure Statement and such documents would be considered. Thus, attached to this Request for Reconsideration is a copy of the First Information Disclosure Statement and accompanying form PTO-1449 filed on August 4, 2003. The Examiner is respectfully requested to return an initialed and signed copy of form PTO-1449.

Appreciation is expressed to Examiner Miggins for his time and attention during the interview that was conducted at the U.S. Patent and Trademark Office on November 17, 2005. The remarks below discuss the substance of the interview.

The undersigned explained during the interview that independent Claim 1 defines a balloon catheter comprising an elongated body and a balloon disposed on the distal side of the elongated body, with the balloon being made from a composite material composed of short-fibers for reinforcement and a matrix resin. As pointed out, Claim 1 goes on to recite that the fibers are oriented in the balloon in such a manner that in a longitudinal cross-section of the balloon 25% or more of the fibers are oriented in the major-axis direction of the balloon while 25% or more of the fibers are oriented in the direction oblique to the major-axis direction, and in a diametrical cross-section of the balloon 8% or more of the fibers are oriented in the circumferential direction of the balloon while 25% or more of the fibers are oriented in the direction perpendicular to the circumferential direction.

The most recent Official Action states that the prior art rejection relying primarily upon International Application Publication No. WO 01/34062 to *Chen et al.* is based on the observation that the percentages recited in independent Claim 1 are open-ended at the upper end and so Claim 1 could be interpreted to read on prior art

in which 100% of the fibers are oriented in the major axis direction. However, as was explained during the interview, Claim 1 recites that in the longitudinal cross-section of the balloon, 25% or more of the fibers are oriented in the major-axis direction of the balloon and 25% or more of the fibers are oriented in the direction oblique to the major-axis direction. The claim further recites that in the diametrical cross-section of the balloon 8% or more of the fibers are oriented in the circumferential direction of the balloon and 25% or more of the fibers are oriented in the direction perpendicular to the circumferential direction. Since the claims recite that 25% or more of the fibers are oriented in the major-axis direction and 25% or more of the fibers are oriented in the direction oblique to the major-axis direction (considered with reference to the longitudinal cross-section of the balloon), these claims cannot be interpreted to read on prior art in which all (100%) of the fibers are oriented in the major-axis direction. Similarly, since the claims recite that 8% or more of the fibers are oriented in the circumferential direction and 25% or more of the fibers are oriented in the direction oblique to such direction (considered with reference to a diametrical cross-section of the balloon), these claims cannot be interpreted to read on prior art in which all (100%) of the fibers are oriented in the major-axis direction.

During the interview, Examiner Miggins inquired into the purpose for constructing the balloon catheter in the manner claimed. The undersigned noted by way of example the discussion at several places in the application (e.g., the middle of page 14 and the middle of page 16) describing that the balloon is not as susceptible as other balloon constructions to the formation of weak portions in the balloon and so the balloon possesses sufficient strength to withstand pressure that

might otherwise contribute to the formation of pin-holes and cracks during balloon dilation. Also, the hoop strength and longitudinal strength of the balloon are improved.

Chen et al. discloses a balloon constructed from a micro-composite material that includes a fibril component and a thermoplastic polymer material. As explained during the interview and discussed in the Amendment filed on July 1, 2005, *Chen et al.* describes at the bottom portion of page four that the fibril component is oriented in a predetermined direction along the longitudinal axis of the balloon. The discussion beginning in line 23 of page seven of *Chen et al.* describes an alternative embodiment in which the fibers are oriented diagonally relative to the longitudinal axis of the balloon. Here, *Chen et al.* describes that the parison 60 has fibers 62 oriented diagonally to the axis in one direction (angle α) at the outset and changing gradually passing through the material to a second direction (angle β) at the inside surface.

As explained during the interview, *Chen et al.* clearly does not recognize that the fibers should be dispersed in a particular manner and does not appreciate that there would be any benefit associated with doing so. Thus, an ordinarily skilled artisan studying the disclosure in *Chen et al.* would not have been led to understand that the disclosed balloon should be constructed so that some percentage of fibers are oriented in the major-axis direction of the balloon while some percentage of fibers are oriented in the direction oblique to the major-axis direction, and so that in a diametrical cross-section of the balloon, some percentage of the fibers are oriented in the circumferential direction while some percentage of the fibers are oriented in the direction perpendicular to the circumferential direction. Further, the disclosure in

Chen et al. would not have motivated one to construct the disclosed balloon so that at least 25% of the fibers are oriented in the major-axis direction of the balloon and at least 25% of the fibers are oriented in the direction oblique to the major-axis direction (in a longitudinal cross-section of the balloon), and so that at least 8% of the fibers are oriented in the circumferential direction while at least 25% of the fibers are oriented in the direction perpendicular to the circumferential direction (in a diametrical cross-section of the balloon).

Thus, for reasons discussed during the interview and set forth above, it is respectfully submitted that *Chen et al.* does not disclose a balloon catheter having the claimed construction set forth above. Further, U.S. Patent Application Publication No. 2003/009310 to *Parsonage* does not make up for the deficiencies pointed out above. Accordingly, a combination of the disclosures in *Chen et al.* and *Parsonage* would not have led one to construct a balloon catheter having the claimed combination of features.

Accordingly, withdrawal of the rejections of record and allowance of application are earnestly solicited.

Should any questions arise in connection with this application or should the Examiner believe that a telephone conference with the undersigned would be helpful

in resolving any remaining issues pertaining to this application the undersigned respectfully requests that he be contacted at the number indicated below.

Respectfully submitted,

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Date: November 29, 2005

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